

HAND SANITIZER- alcohol liquid
Soluciones Cosmticas SA de CV

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

FRAGRANCE FREE

BERSIH

ALCOHOL HAND SANITIZED GEL

SUPPORTS KILLING
99.9%
OF GERMS*

Net wt. 16.9 fl oz (500ml)

Drug Facts	
Active Ingredient	Purpose
Ethyl alcohol 70%.....	Antiseptic
Uses	
• Recommended for aseptic hand cleansing. This product does not replace the use of soap & water.	
• This product does not replace the use of soap & water. Recommended for repeated use.	
Warnings	
For external use only.	
When using this product:	
Avoid contact with eyes. In case of accidental contact, flush eyes thoroughly with water for 15 minutes. Avoid contact with broken skin or if you have allergies to any ingredients.	
Stop use and consult a doctor if skin irritation occurs.	
Keep out of reach of children. If swallowed get medical help at a Poison Control Center immediately.	
FLAMMABLE: Keep out of heat.	
Directions:	
• Place a small amount of product in your hand.	
• Rub hands together briskly for at least 30 seconds until dry.	
• Children under 6 years of age should use adult supervision	
Inactive ingredients	
Water, Propylene Glycol, Carbomer, Sodium Hydroxide.	
Questions? 52-55-5685-62-16	
 7 503007 103178	
Elaborated by: Soluciones Cosméticas, S.A. de C.V. Año de Juárez No. 110. Col. Granjas San Antonio. Iztapalapa, Mexico City. Zip Code 09070	
Distributed by: Private D Capital Group Corp 16901 Collins Avenue, Suite 2003 Sunny Isles Beach, FL Zip Code 33160	
Made in Mexico	
*With a correct hand washing technique	

500 mL NDC: 75165-000-01

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75165-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	1.36 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75165-000-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Soluciones Cosmticas SA de CV (814818001)

Registrant - Soluciones Cosmticas SA de CV (814818001)

Establishment

Name	Address	ID/FEI	Business Operations
Soluciones Cosmeticas, S.A. de C.V.		814818001	manufacture(75165-000)

Revised: 4/2020

Soluciones Cosmticas SA de CV